REMARKS

Claim Amendment

Claim 1 has been amended to more particularly point out that a pharmaceutical composition of the invention comprises either a single pharmaceutical agent represented by Formula (I), or an agent of Formula (I) in combination with an antibacterial agent, an antiviral agent, an anti-inflammatory agent or an antibiotic agent. Support for this amendment is found in the previously amended Claim 1 and on page 22, lines 20-32.

Claim 2 has been amended to more particularly point out that a pharmaceutical tablet composition of the invention comprises either a single pharmaceutical agent *N*-ethyl-*N'*-(3-dimethylaminopropyl) urea or a salt thereof or *N*-ethyl-*N'*-(3-dimethylaminopropyl) urea or a salt thereof in combination with one or more ingredients selected from the group consisting of an antibacterial, an anti-viral, an anti-inflammatory agent and an antibiotic. Support for this amendment is found in the previously amended Claim 2.

Claim 12 has been amended to correct its dependency. Claim 12 now depends directly on Claim 1.

Claims 72 and 74 have been amended to more particularly point out that a pharmaceutical injectable composition (Claim 72) and a pharmaceutical aerosol composition (Claim 74) of the invention comprise either a single pharmaceutical agent *N*-ethyl-*N'*-(3-dimethylaminopropyl) urea or a salt thereof or *N*-ethyl-*N'*-(3-dimethylaminopropyl) urea or a salt thereof in combination with one or more ingredients selected from the group consisting of an antibacterial, an anti-viral, an anti-inflammatory agent and an antibiotic. Support for this amendment is found in the previously amended Claims 72 and 74.

New Claim 76, dependent on Claim 1, recites that the pharmaceutical composition is a tablet. Support for this claim is found throughout the specification and in particular in Claim 2. New Claim 77, dependent on Claim 1, recites that the pharmaceutical composition is an aerosol. Support for this claim is found throughout the specification and in particular in Claim 74. New Claim 78, dependent on Claim 1, recites that the carrier of the pharmaceutical composition is sterile water. Support for this amendment is found throughout the specification and in particular in Claim 72.

New Claim 79 recites that the pharmaceutical composition consists essentially of the enumerated elements. New Claim 80, dependent on Claim 79, is directed to a specific active compound of Formula (I). New Claim 81 is directed to a pharmaceutical composition that consists essentially of the enumerated elements. New Claim 82, dependent on Claim 81, is directed to a specific active compound of Formula (I). New Claim 83, dependent on Claim 81, is directed to a composition of Claim 1 that includes an antibacterial, an anti-viral or an anti-inflammatory agent or an antibiotic.

This amendment introduces no new matter.

Rejection of Claim 1, 4 and 11-21 under 35 U.S.C. §112, First Paragraph

Claim 1, 4 and 11-21 are rejected under 35 U.S.C. §112, first paragraph, as lacking written support. The Examiner stated that the recitation of G2 as -N(R1R2) and -CN(R1R2) does not find support in the written description as these groups are not discussed on page 2, lines 34-35 of the specification as filed. The Examiner further stated that the present disclosure recited G2 as having a net charge and does not recite that G2 can be a neutral species. The Examiner further stated that while the original Claim 2 provides support for a neutral G2, recitation of one species does not support a claim to a genus.

Applicants respectfully disagree. In the Amendment submitted on May 27, 2004, Applicants argued that on page 25, lines 33-34, the instant specification discloses that the composition of the invention can be administered "per se (neat) or in the form of a pharmaceutical salt" and that this recitation supports a claim to a neutral compound. In response, the Examiner stated that *the combination of G2 and Z* may result in a neutral compound that may be a salt, but that there is no disclosure of *G2 having a neutral charge*. Applicants note that the recitation in the alternative of the neat compound ***or*** a pharmaceutical salt implies that ***the neat compound is neutral*** since a non-neutral compound would form a salt in a pharmaceutically acceptable carrier and would be properly qualified as a "pharmaceutical salt". Therefore, "neat" clearly must be neutral. It appears, however, that the Examiner does not consider a "neat" compound to be neutral, implying that a "neat" compound may be a free base. If Applicants are incorrect, a clarification is requested.

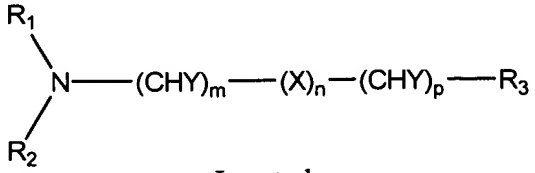
Furthermore, the instant specification as filed discloses on page 2, line 33 to page 3, line 2 that G2 as a group selected from a heterocycle, a -CN(R1R2R3) or -N(R1R2R3). R1-R3 are defined to include a hydrogen. Applicants direct the Examiner's attention to pages 9 to 11 of the instant specification. Among the disclosed examples of the compounds of the invention, there are those with G2 represented by -CN(HR1R2) and -N(HR1R2). Applicants note that a moiety -NR1R2 is a Lewis base and therefore moieties $[-NR1R2]^0$ and $[-NHR1R2]^+$ exist in equilibrium in a solvent. While in aqueous solvents, the charged moiety is prevalent, in aprotic organic solvents the neutral species dominate. Applicants submit that for any solvent, both species will be present, albeit in different proportions. Accordingly, a charge species is not separable from an uncharged species in solution and thus disclosure of one is implicit in disclosure of another. This is acknowledged by reciting in Claim 1 that "the charge of Z depends on the charge of G_2" which clearly indicates that as the Lewis base protonates and deprotonates in solution, the charge and/or number of the associated counterbalancing ions will change correspondingly.

It follows therefore that the recitations of -NR1R2, -CN(R1R2) and the neutrality of G2 in Claim 1 amount to restatement of the fact that both a protonated and a deprotonated forms of Lewis base exist in a solution. As this is a common knowledge among those skilled in the art, the disclosure cannot be deemed defective in supporting such recitations.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 U.S.C. §102(b) over Ito *et al.*

Claim 1 is rejected under 35 U.S.C. §102(b) over U.S. Pat. No. 5,506,151 to Ito *et al.* Ito discloses a composition that suppresses non-specific binding of antigens to non-cognate antibodies in immunosorption assays (for example, ELISA). These compositions, well known in the art, disrupt hydrogen bonds, which are responsible for antibody-antigen binding, by altering the ionic strength of the solvent achieved by adding charged species capable of forming hydrogen bonds to the solution. The composition of Ito includes a compound of formula



Ito et al.

wherein

X is -NH-(CO)-NH-, -NH-(CS)-NH-, or -N = C = N-,

R1 and R2, which may be the same or different, are C1 -C5 linear or branched alkyl groups, or R1 and R2, together with nitrogen, form an N-linked morpholine moiety or the metho-p-toluenesulfonate salt thereof,

Y, which may be the same or different, is any of H, OH and halogen,

R3 is --NR1R2, --NH2, --CHY, cyclohexyl, or H,

m is an integer of from 2 to 5, p is an integer of from 0 to 5, and n is 0 or 1,

and the acid addition salts thereof. An example of a compound of Ito is N-ethyl-N'-(dimethylaminopropyl) urea (EDU).

The Examiner stated that a "pharmaceutically acceptable carrier" as disclosed in the instant specification and exemplified by sterile water, does not distinguish Claim 1 from Ito because Claim 1 does not recite "sterile aqueous solvent". The Examiner stated that Claim 1, when read as broadly as possible, encompasses compositions that are not sterile.

The Examiner further stated that a skilled artisan practicing the invention of Ito would have used sterile water to eliminate factors that may affect the result of antigen-antibody binding experiment.

Applicants submit that Claim 1 as amended is neither anticipated, expressly or inherently, nor made obvious by Ito.

Claim 1 as amended is novel over Ito because Ito does not *expressly* recite that his solvent is a "pharmaceutically acceptable carrier". Such an *express* recitation is an element of Claim 1.

In response to the Examiner's statement regarding the desirability of using sterile water, Applicants note that if the Examiner proposes that to obtain the invention of Applicants' Claim 1 one skilled in the art, while practicing the invention of Ito, *needs to select* sterile water over non-sterile water, then the rejection based on novelty is improper because there is no indication in Ito that such a selection was made.

Since Ito lacks *express* teaching of a pharmaceutically acceptable carrier or a *selection* of sterile water as such a carrier, it is Applicants' understanding that the Examiner's statement that

Claim 1, when read as broadly as possible, encompasses compositions that are not sterile amounts to a rejection of Claim 1 as *inherently* anticipated by Ito.

Recapitulating the arguments presented in the Amendment of May, 27, 2004, submitted along with a Request for Continuing Examination, Applicants note that Ito used water that may or may not have been pharmaceutically acceptable. Indeed, Ito gives no indication whether a pharmaceutically acceptable water was used or even that such water was desirable. Absent such teaching, the Examiner's statement that a skilled artisan practicing the invention of Ito would have used pharmaceutically acceptable water to eliminate factors that may affect the result of antigen-antibody binding experiment amounts to an assertion that using sterile water was *possible*.

It is well established in Patent Law, however, that a novelty rejection based on inherency cannot be maintained if it is merely "possible" that the prior art discloses all of the claim limitations:

> The PTO Board erred in holding that a prior art reference anticipated by inherency an applicant's claim, which concerned a diaper fastening and disposal system. The Board's analysis rested on mere probability or possibility, i.e., that elements in the reference could be used other than as disclosed and for a different function, which is not sufficient to establish inherency. *In re Robertson,* 49 USPQ2d 1949 (Fed. Cir. 1999).
>
> To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill. *In re Robertson,* 49 USPQ2d 1949 (Fed. Cir. 1999) quoting *Continental Can Co. v. Monsanto Co.* . . . Fed. Cir. 1991).
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> Inherency, however, may not be established by probabilities or possibilities, The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Robertson,* 49 USPQ2d 1949 (Fed. Cir. 1999) quoting *In re Oelrich* 212 USPQ 323, 326 (CCPA 1981).

Because it cannot be determined whether Ito used sterilized water, the novelty rejection is improper and should be withdrawn.

Finally, Applicants note that the Examiner's statement regarding the desirability of using pharmaceutically acceptable water amounts to a *suggestion to modify* the teaching of Ito to arrive

at the present invention. Such a rejection should properly be qualified as an obviousness rejection.

Claim 1 is non-obvious over Ito because a skilled artisan practicing the invention of Ito would ***not*** be motivated to use a pharmaceutically acceptable carrier as a solvent. Indeed, it is well-known in the art that a pharmaceutically acceptable solvent typically requires distillation, deionization through a filter with nanometer-size pores, and, crucially, needs to be pyrogen-free. Preparation of a pharmaceutically acceptable solvent is costly and lengthy. However, a solvent that is merely de-salted and filtered through a micron-size pores is adequate for an immunoprecipitation experiment. Elimination of pyrogen from an ELISA reagent is certainly not a standard practice. It follows that, when given a choice between a cheaper "adequate" solvent and an expensive "pharmaceutically acceptable" one, a skilled artisan practicing the invention of Ito would chose the "adequate".

Applicants further present new Claims 76-78 and 83 dependent on Claim 1. Claims 76 and 77 recite that the pharmaceutical composition is a tablet or an aerosol, respectively. New Claims 76 and 77 are novel in view of Ito. As mentioned above, Ito discloses a composition that suppresses non-specific binding of antigens to non-cognate antibodies in immunosorption assays (for example, ELISA). To the best of Applicants' knowledge, immunosorption assays are not manufactured in a "tablet" or an "aerosol" formats. Accordingly, Ito does not teach either a tablet or an aerosol. Claim 78 recites that the carrier is a sterile water. New Claim 78 is novel over Ito because Ito does not teach that his solvent be sterile. Nor is it obvious in view of Ito because even if elimination of impurities were contemplated by a skilled artisan practicing the invention of Ito with a view to improve the results of antigen-antibody binding assays, ***sterilization*** of the composition of Ito is neither taught, nor suggested, nor desired for the reasons outlined above. New Claim 83 is novel and non-obvious over Ito because it recites elements that are neither taught not suggested by Ito.

For similar reasons, new independent Claim 79 and new Claim 80 dependent thereon are novel and non-obvious over Ito.

Additionally, new Claim 79 recites a composition that *consists essentially of* a pharmaceutically acceptable carrier and a compound of formula (I). Applicants note that MPEP §2111.03 explains that:

> [t]he transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976)

Thus, new Claim 79 excludes therapeutic ingredients not specified in the claim, but encompasses binders, carriers, excipients and other drug vehicles that do not affect the therapeutic properties of the claimed combination. Applicants note that the practice of the invention of Ito requires the presence of an "immunoreactant", i.e. an antigen or an antibody (column 4, lines 30-40). The presence of an antigen or an antibody in a pharmaceutical composition of Claim 79 would materially affect its basic characteristics and is thus excluded. Applicants further note that the property of the claimed invention of being "pharmaceutically acceptable" would be affected if non-sterile water were the carrier. Since sterile water carrier is not an express or implicit part of the teaching of Ito, new Claim 79 is not anticipated by Ito.

Applicants also present new independent Claim 81 and new Claim 82 dependent thereon. New Claim 81 recites that the pharmaceutical composition consists essentially of a compound of formula (I) and a compound selected from one or more of an antibacterial agent, an anti-viral agent, an anti-inflammatory agent and an antibiotic agent. Since Ito neither teaches nor suggests such a combination, new Claim 81 is novel and non-obvious over Ito.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 U.S.C. §102(b) over Beuvery *et al.*

Claim 1 is rejected under 35 U.S.C. §102(b) over Beuvery *et al.*

The Examiner stated that Claim 1 recites that the pharmaceutical composition ***comprises*** the enumerated ingredients and thus does not exclude the composition "of EDU and a vaccine" as taught by Beuvery.

Beuvery teaches the preparation of a conjugate of Meningococcal group C polysaccharide and tetanus toxoid (a carrier polypeptide) for the purpose of developing an anti-meningitis vaccine. The conjugate is prepared by coupling tetanus toxoid and the polysaccharide with *N*-ethyl-*N'*-(diethylaminopropyl) carbodiimide (EDC).

Beuvery teaches that while such a conjugated vaccine may be safe for human use, EDC fails as a linking agent due to instability of the resulting product and low reactivity with carrier polypeptide (Beuvery, the paragraph bridging pages 118 and 119). Consequently, the method of preparation of the vaccine of Beuvery results in the batches that necessarily contain by-products (Beuvery, page 119, lines 2-5 from the top). ***As one of these by-products, N-Ethyl-N'-(diethylaminopropyl) urea (EDU) is formed.*** Beuvery teaches that EDU is a non-reactive derivative of EDC (page 118, the last line).

Applicants have amended Claim 1 to recite that the pharmaceutical composition comprises ***either*** a single pharmaceutical agent represented by Formula (I) ***or*** a compound represented by Formula (I) in combination with one or more of an antibacterial agent, an anti-viral agent, an anti-inflammatory agent and an antibiotic agent. Since the composition of Beuvery *always includes* a pharmaceutical agent other than a compound of Formula (I) of Applicants' Claim 1 (*i.e.* the polysaccharide-toxoid conjugate vaccine) and *never includes* an antibacterial agent, an anti-viral agent, an anti-inflammatory agent or an antibiotic agent, Beuvery does not anticipate Claim 1 as amended.

Applicants further submit that new independent Claims 79 and 81 are novel in view of Beuvery. New Claims 79 and 81 recite pharmaceutical compositions that *consist essentially of* the elements enumerated in the claims at issue. As submitted above by Applicants, this language excludes ingredients that affect the therapeutic properties of the claimed combinations. Beuvery, however, contains a therapeutic agent (a vaccine) other than the one recited in Applicants Claims 79 and 81 (a compound of Formula (I)). It follows that the vaccine of Beuvery is excluded and new Claims 79 and 81 are not anticipated by Beuvery.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1, 2, 4, 11-21, 72 and 74 Under 35 U.S.C. §103(a) over Beuvery *et al.*

Regarding Claim 1 and claims dependent thereon

It is Applicants' understanding that Claims 1 and Claims 4 and 11-21, dependent thereon, are rejected as obvious over Beuvery.

Applicants note that the Examiner failed to expressly provide her argument in support of this position. The Examiner is referring to section 8 of the Office Action as containing the relevant arguments; however, Applicants believe that the Examiner meant to refer to section 9 of the Office Action. It is Applicants' understanding that the relevant portion of section 9 of the Office Action states that Claim 1 is obvious in view of Beuvery because "the composition taught by the reference [*i.e.* Beuvery] is encompassed by the instant claims". If Applicants' understanding is incorrect, clarification is requested.

Where the claimed invention is rejected as *prima facie* obvious in view of a combination of references, M.P.E.P.§ 2142 requires that:

> "[t]o establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

Applicants submit that not only does Beuvery fail to teach all elements of Claim 1 as amended, but that no skilled artisan practicing Beuvery's teachings would modify the latter to obtain the subject matter of Claim 1.

Indeed, as mentioned above, Claim 1 as amended recites that the pharmaceutical composition comprises ***either*** a single pharmaceutical agent represented by Formula (I) ***or*** a compound represented by Formula (I) in combination with one or more of an antibacterial agent, an anti-viral agent, an anti-inflammatory agent and an antibiotic agent. Beuvery, on the other hand, discloses a pharmaceutical composition that delivers a pharmaceutical agent other than a compound of Formula (I) (*i.e.* a vaccine) and further contains a EDU as an unreactive contaminant. Accordingly, Beuvery does not teach all the elements of Claim 1 as amended.

Beuvery teaches that EDU is a non-reactive byproduct (page 118, the last line) of the process used to prepare the pharmaceutically active agent of Beuvery, the vaccine (Beuvery, page 119, lines 2-5 from the top). To arrive at the invention of Claim 1, one skilled in the art would need to be motivated to either produce a composition that includes EDU as a single pharmaceutically active ingredient, or add an antibacterial agent, an anti-viral agent, an anti-inflammatory agent or an antibiotic agent to the composition of Beuvery. However, Beuvery teaches that EDU is inactive. Accordingly, one skilled in the art would not be motivated to

manufacture a composition that includes this "inactive" ingredient as a single pharmaceutical agent. Furthermore, Beuvery discloses that his vaccine does not meet the chemical requirements imposed on its active ingredient, Meningococcal group C polysaccharide conjugated to tetanus toxoid by EDC. Namely, EDC fails as a linking agent due to instability of the resulting product and low reactivity with carrier polypeptide (Beuvery, the paragraph bridging pages 118 and 119). It follows that one skilled in the art would not be motivated to modify a composition that delivers a vaccine that does not work properly by adding to it an antibacterial agent, an anti-viral agent, an anti-inflammatory agent or an antibiotic agent. There is, furthermore, no conceivable reason for such a modification: pharmaceutical preparations comprising combinations of a vaccine and a therapeutic agent are not widely known in the art.

Applicants submit that one skilled in the art would not be motivated to modify a composition of Beuvery to arrive at the subject matter of Claim 1 as amended. Reconsideration and withdrawal of the rejection are respectfully requested.

For similar reasons, new independent Claims 79 and 81 are non-obvious in view of Beuvery. As submitted above by Applicants, the language of these claims excludes ingredients that affect the therapeutic properties of the claimed combinations. It follows that the vaccine of Beuvery is excluded from the subject matter claimed in Claims 79 and 81. Thus, to arrive at the invention of new Claims 79 and 81, one skilled in the art would need to modify the vaccine of Beuvery by removing the very ingredient that Beuvery's preparation is formulated to deliver. Applicants submit that a skilled artisan would ***not*** be motivated to so modify the preparation of Beuvery. Furthermore, in view of Beuvery's teaching that EDU is inactive, one skilled in the art would not be motivated to manufacture a composition that includes this "inactive" ingredient as a sole pharmaceutical agent.

Regarding Claims 2, 72 and 74

Claims 2 and 72 are rejected as obvious over Beuvery under Ex parte Douros, 163 USPQ 667 (PO Bd App. 1968). It is Applicants' understanding that independent Claim 74 is rejected by relying on the same argument.

The Examiner stated that under Ex parte Douros, the addition of a carrier or solvent to an unpatentable compound renders an unpatentable composition. The Examiner stated that

preparation of a solid or an aerosol is *prima facie* obvious. It is Applicants' understanding that, by implication, it is the Examiner's position that addition of a sterile liquid carrier to N-ethyl-N'-(dimethylaminopropyl) urea (Claim 72) is also obvious.

Applicants submit that Claims 2, 72 and 74 of the instant case are not like Claims 23-25 of U.S. App. Serial No. 571,363, presented on appeal by Douros, and more similar to Claims 1-4 of U.S. App. Serial No. 185,865 presented on appeal in Ex parte Ruschig, 147 USPQ 47 (PO Bd App. 1965), a copy of which is enclosed for the Examiner's convenience.

In Douros, Applicants claimed a composition comprising a heretofore known compound, dissolved in a carrier or solvent, for a purpose recited in the preamble. (163 USPQ 667) Accordingly, the Board held that a claim reciting a "composition for use as an effective algaecide" was obvious where the contribution of Applicants was to add a solvent to the active ingredient. The Board of Douros stated:

> The recital in the claims of the intended use of the composition does not patentably distinguish it from an aqueous solution thereof. (163 USPQ 668).

In contrast, in Ruschig, Applicants claimed a composition comprising a known compound and pharmaceutically acceptable excipients in a heretofore unknown form (tablet) for a heretofore unknown purpose (oral administration). (147 USPQ 46) The Board held that while placing a substance in a tablet form is obvious, claims of this character are allowed where the use of the composition for a particular purpose is an inventive contribution. Referring to Claims 1-4 of U.S. App. Serial No. 185,865 by Ruschig, drawn to a tablet for oral administration containing an active material, the Board of Ruschig stated:

> ... [C]laims of this character are sometimes allowed in view of the nature and recognition of the discovery involved, that is, the use of the particular substances for the particular purpose [...] (147 USPQ 47)

Applicants note that the Board of Douros distinguished its decision from that of Ruschig, thus indicating that appropriately formulated claims to pharmaceutical compositions can be non-obvious over known active ingredients under Ruschig:

> In the Ruschig et al. decision, the claim was worded differently from the instant claims. Moreover, the Ruschig et al. composition has received recognition and acceptance in the art as a break-through in the oral treatment of diabetes. (163 USPQ 668)

Applicants posit that Ex Parte Ruschig establishes a criterion of non-obviousness of a pharmaceutical composition comprising a known active substance and inactive diluents and excipients. Namely, such a composition is non-obvious if the use of the active substances for the particular purpose and/or the attendant mode of administration are novel. Applicants submit that Claims 2, 72, 74 as well as new Claim 81 are non-obvious under Ruschig.

The claims at issue are novel. Indeed, Claims 2, 72, 74 as amended and new Claims 76 and 77 exclude a vaccine, which is *always* present in a composition of Beuvery. Furthermore, the prior art is silent on the form of administration: either oral (tablet, recited in Claim 2 and new Claim 76, dependent on Claim 1) or nasal-pulmonary (aerosol, recited in Claim 74 and new Claim 77, dependent on Claim 1) or administration of an injectable composition as recited in Claim 72 as amended or a pharmaceutical composition as recited in new Claim 81.

To show that Claims 2, 72, 74, as amended, and new Claims 76, 77 and 81 are not obvious over Beuvery under Ruschig, Applicants need to show that either the use of the composition for a particular purpose or its form (*i.e.* a mode of administration) is inventive over Beuvery.

Beuvery is silent on the use of compounds of formula (I), including N-ethyl-N'-(dimethylaminopropyl) urea (EDU), for therapeutic purposes. Beuvery teaches a composition comprising an unsuccessful vaccine and clearly considers EDU an inactive contaminant. Accordingly, a skilled artisan would not be motivated to administer to a patient a composition comprising an "inactive" contaminant of Beuvery or a composition comprising a combination of a failing vaccine and another therapeutic agent (an antibacterial, an anti-viral, an anti-inflammatory agent or an antibiotic).

Applicants, on the other hand, have demonstrated pharmaceutical utility of a class of compounds heretofore thought inactive. Namely, Examples 8 through 22 of the specification as filed demonstrate that compounds of Formula (I) and salts thereof alleviate the symptoms of inflammatory conditions. Based on this discovery, Applicants' developed a tablet, an aerosol and injectable compositions, including ones comprising sterile water for the purpose of administering such pharmaceutical compositions to a patient. It follows therefore, that the

purpose for which the instant compounds and the compositions comprising same are used by Applicants, administering a pharmaceutical compositions comprising compounds of Formula (I), is inventive.

Furthermore, the modes of administration are also inventive in view of Beuvery. One skilled in the art would hardly be motivated to place a compound referred to by Beuvery as an "inactive" contaminant in either tablet or aerosol form, or administer an injectable composition which either excludes the vaccine or includes additional pharmaceutically active ingredients, as recited in Claim 72 as amended or a pharmaceutical composition as recited in new Claim 81 is taught or suggested in Beuvery.

Applicants submit that the Claims 2, 72, 74, and new Claims 76, 77 and 81 satisfy the criterion of Ruschig and are therefore not obvious.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1, 2, 4, 11-21, 72 and 74 Under 35 U.S.C. §103(a) over Ito *et al.*

Claims 1, 2, 4, 11-21, 72 and 74 are rejected under 35 U.S.C. §103(a) over U.S. Pat. No. 5,506,151 to Ito *et al.*

The Examiner stated that the instant claims differ from Ito by "encompassing compositions not exemplified in the reference". The Examiner further stated that addition of a carrier or a solvent to an unpatentable compound is *prima facie* obvious under Ex parte Douros (supra).

It is Applicants' understanding that the Examiner asserts that the difference between the claims at issue and Ito is in the addition of a particular solvent and that the analysis applied by the Examiner in advancing the rejection of the claims at issue over Beuvery under Ex parte Douros equally applies with respect to Ito.

Applicants recapitulate the arguments presented in the previous section of the instant Amendment.

The claims at issue are novel over Ito as argued above by Applicants. To show that claims at issue are not obvious over Ito under Ruschig, Applicants need to show that either the use of the composition for a particular purpose or its form (*i.e.* a mode of administration) is inventive in view of Ito.

The prior art of record is silent on the use of compounds of formula (I), including N-ethyl-N'-(dimethylaminopropyl) urea (EDU), for therapeutic purposes. In fact, Ito does not contemplate a pharmaceutical composition at all and uses his composition as a blocking solution for immuno-sorbent assays such as ELISA. Accordingly, an artisan practicing the invention of Ito will not be motivated to administer a composition of Ito to a patient. It follows therefore, that the purpose for which the instant compounds and the compositions comprising same are used, administering a pharmaceutical compositions comprising compounds of Formula (I), is inventive.

Furthermore, since the compositions of Ito lack therapeutic utility, one skilled in the art would hardly be motivated to create a tablet, an aerosol or even a pharmaceutical composition that includes sterile water.

Applicants submit that the Claims 2, 72, 74, and new Claims 76, 77 and 81 satisfy the criteria of Ruschig and are therefore not obvious.

Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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Dated: 12/21/04

Patent Office Board of Appeals

Ex parte RUSCHIG, AUMÜLLER, KORGER, WAGNER, SCHOLZ, AND BÄNDER

Patent issued Aug. 3, 1965

Opinion dated Mar. 4, 1965

PATENTS

1. Words and phrases (§ 70.)

Claims are not restricted to tablets to be used in treatment of diabetes in view of use of "suitable"; rather than stating "a tablet for oral administration" etc., claims state "a tablet suitable for" etc., which expression is not necessarily limitative.

2. Patentability—Composition of matter (§ 51.30)

While compounds are obvious as such and while the placing of a substance in tablet form is trivially obvious, claim to a tablet used in treatment of specific disease is patentable in view of the nature and recognition of discovery involved, i.e., use of particular substance for the particular purpose, as supplementing the protection afforded by method of use claims.

3. Specification — Sufficiency of disclosure (§ 62.7)

Although compound is within scope of general disclosure, it is not adequately supported thereby since approximately half a million different compounds would appear to be included in such disclosure; specification gives general formula with three variable substituents; if proper choices are made, instant compound is produced, but the particular selection is not indicated; broad disclosure with a variety of specific examples does not entitle applicants to present specific claims to another example which has not been mentioned.

Particular patents—Medicine

3,198,706, Ruschig, Aumüller, Korger, Wagner, Scholz, and Bänder, Methods of Reducing Blood Sugar and Compositions Therefor, claims 1, 2, 4 to 6, and 8 of application allowed; claims 3 and 7 refused.

Appeal from Group 120.

Application for patent of Heinrich Ruschig, Walter Aumüller, Gerhard Korger, Hans Wagner, Josef Scholz, and Alfred Bänder, Serial No. 185,865, filed Apr. 9, 1962. From decision rejecting claims 1 to 8, applicants appeal (Appeal No. 283-74). Affirmed as to claims 3 and 7; reversed as to claims 1, 2, 4 to 6, and 8.

See also 145 USPQ 274.

CURTIS, MORRIS & SAFFORD, New York, N.Y., GEORGE E. FROST, Chicago, Ill., and EUGENE O. RETTER, Kalamazoo, Mich., for appellants.

Before FEDERICO and ROSA, Examiners in Chief, and STONE, Acting Examiner in Chief.

FEDERICO, Examiner in Chief.

This is an appeal from the final rejection of claims 1-8, all the claims in the application.

The claims are predicated upon the discovery that certain compounds can be effectively used for lowering the blood sugar in the oral treatment of diabetes. Claims 1-4 are expressed as a tablet containing the active material and claims 5 to 8 are directed to the process for lowering blood sugar in the treatment of diabetes which comprises orally administering the particular compound or one of a particular group of compounds.

The present application is based on application 601,107, filed July 31, 1956. In the prior application we affirmed the rejection of claims 1, 2, 3 and 13, directed to chemical compounds or groups of chemical compounds on the ground that the compounds were obvious in view of the prior art. Claims 1, 2, 4 and 3 are respectively parallel to the above mentioned claims of the prior application in that the compounds recited are identical and expressed in identical terms. Claims 5, 6, 8 and 7 are similarly respectively parallel to the claims of the prior application. The claims of the present application are directed to the use of the compounds claimed in the parent application.

The claims stand rejected as being obvious in view of certain cited references, some of which are the same as the references cited in the parent application in connection with the compounds. The issue involved in the present case, however, is considered different from the issue involved in the parent application since we are here concerned with the use of certain compounds for a specific purpose, a discovery different from the formation of compounds not restricted to any particular use.

Appellants have submitted an extensive brief relating to this issue, which thoroughly and extensively treats the matter. We consider it superfluous to review the arguments advanced or summarize the various exhibits and affidavits. We are convinced that the rejection as being obvious is untenable, without necessarily agreeing with every statement made in appellants' brief.

[1] The above remarks apply to the method of treatment claims 5 to 8. Claims 1 to 4 for a tablet are indicated as being unpatentable since the combination of a substance and appropriate diluents in tablet form is conventional, the compounds themselves being considered unpatentable. Appellants indicated at the hearing that they intended claims 1 to 4 to be limited to tablets to be used in the treatment of diabetes. However, we do not regard the language as being so restricted in view of the use of the word "suitable;" rather than stating "A tablet for oral administration, etc.", the claims state "A tablet suitable for, etc.," which expression is not necessarily limitative. With respect to the position of the examiner as to these claims, while we agree that the [2] compounds are obvious as such and that the placing of a substance in tablet form is trivially obvious, claims of this character are sometimes allowed in view of the nature and recognition of the discovery involved, that is, the use of the particular substances for the particular purpose, as supplementing the protection afforded by the method of use claims. With this view we recommend that this rejection as to claims 1 to 4 be withdrawn if the claims are amended by cancelling the word suitable." At the hearing counsel indicated concurrence with such a recommendation if made.

We find it necessary to make a new ground of rejection of claims 3 and 7. These claims are specific to the use of N-(4-chlorobenzenesulphonyl)-N'-propylurea. These claims are rejected on the ground of descriptions in prior printed publications more than one year prior to the filing of the present application and public use and sale in this country more than one year prior to the filing of the present application. These facts are well known to appellants' counsel, and those interested in this application by unrecorded interests, and the citation of particular references is unnecessary. The file of Interference No. 89,010 in which the parent application was involved on the basis of a claim to the compound of these claims shows the citation of numerous publications more than one year old, some of which are cited in the present record and the use and sale to which reference has been made is notorious and appellants have even alluded to this fact. An interference on the particular compound has been referred to. Oral antidiabetic preparations of this compound have been on the market for some time by the assignee of the other party to the interference, under the name of Diabinese. Reference 7 referred to in appellants' brief indicates that the preparation was introduced for clinical trial in the United States late in 1957 and it appears that the drug was placed on the market a year later. Appellants can supply more precise dates if they desire. The brief has appended to it a printed circular of the manufacturer which indicates that it was "Reissued October 1960." Other publications dealing with the work of the other party have also been referred to by appellants.

In order to overcome the dates of the publications, and uses and sales it is necessary for claims 3 and 7 to be given the benefit of the filing date of the parent application, and it is held that Application No. 601,107 does not contain an adequate support for these claims and that these claims would be improper in that application. Therefore the present application is not considered entitled to the filing date of Application 601,107 as to these claims.

The compound referred to in the two claims under consideration is not specified in application 601,107 although it is included within the scope of the general disclosure.

[3] Pages 1 and 2 of the specification of 601,107 give a general formula with three variable substituents indicating their nature. If the proper choices are made, the compound in question is produced, but nowhere in the specification is the particular selection indicated. Considering the substituents which are disclosed and the variations and limits indicated, with the isomers of each radical and the various positions on the ring (but not counting variations in the location of the double bond in the alkenyl radicals) a total of approximately half a million different compounds would appear to be included. Pages 2, from line 22 to page 9, line 17, describe methods of preparing compounds of the class involved. Here again there is no reference to the compound in question. There is, on page 8, the inclusion of propylamines in a list of 19 amines which may be used "For the reaction with the compounds mentioned above." If the "mentioned above" means the immediately preceding paragraph then this reference is wholly irrelevant, if not, it is only part of the general disclosure.

In holding that there is or would be no right to make the particular specific claims in the parent application, we do not intend to suggest in any way that appellants are not entitled to the generic claims presented in this case, which, incidentally, are not quite of the same scope as the generic disclosure which has been referred to. The disclosure in the present and in the parent applica-

tion is quite broad with a variety of specific examples, and a basis is laid for the presentation of generic claims to which no objection is raised by the examiner by reason of their scope, nor do we raise any objection.

The issue raised is whether the broad disclosure with a variety of specific examples would entitle appellants to present specific claims to another example which has not been mentioned. We think not.

With generic claims 1, 2, 5 and 6, there is no need for specific claims 3 and 7 except for forensic strategic purposes and, more important, to fall back on as a separate invention in the event that the generic claims turned out to be invalid. But does the specification of 601,107 entitle this to be done? The impropriety of claims 3 and 7 with respect to 601,107 is readily apparent by considering the transformations which would be necessary in that specification if claims 3 and 7 were the only claims presented therein. Examples 1 to 11, page 14, line 18 to page 23, all the examples in the case, would need to be cancelled as irrelevant to the claims. The tables of tests on pages 12 and 13 would likewise need to be cancelled. The general disclosure on pages 1 and 2 would need to be replaced by the naming of one compound only, which is not mentioned anywhere. The various methods described on pages 2 to 9 would need to be shorn of a good many irrelevancies and a method reconstructed referring to the one compound. And various general statements throughout the remainder of the specification would need to be cancelled or amended to refer to a single compound not previously specified. In other words a completely reconstructed specification.

The decision of the examiner is reversed as to claims 5 to 8, and is affirmed as to claims 1 to 4 with a recommendation. A new rejection under Rule 196(b) is made of claims 3 and 7.

Any request for rehearing or reconsideration or modification of this decision by the Board of Appeals based upon the same record must be filed within thirty days from the date of the decision. (Rule 197). Should appellants elect to have further prosecution before the examiner in response to the new rejection under Rule 196(b) by way of amendment or showing of facts, or both, not previously of record, a shortened statutory period for making such response is hereby set to expire sixty days from the date of this decision.

Patent Office Board of Appeals

Ex parte BUDD

Patent issued Aug. 24, 1965

Opinion dated May 27, 1965

PATENTS

1. Claims—Article defined by process of manufacture (§ 20.15)

Claims—Process (§ 20.80)

Method claims are not rejected as being nothing more than obvious manner of producing applicant's article; where it is not apparent whether the invention lies in article or in method of producing article, method claims should be allowed along with article claims.

2. Pleading and practice in Patent Office—Rejections (§ 54.7)

Sequence of steps in method claims must be shown to be old by citation of art, and not by argument, to establish its obviousness and support rejection.

Particular patents—Packing Insert

3,202,335, Budd, Cushioned Packing Insert, claims 3 to 6 of application allowed.

Appeal from Group 460.

Application for patent of Larry J. Budd, Serial No. 228,174, filed Oct. 3, 1962. From decision rejecting claims 3 to 6, applicant appeals (Appeal No. 349-96). Reversed.

CHARLES F. MERONI, JR., and HILL, SHERMAN, MERONI, GROSS & SIMPSON, both of Chicago, Ill., for applicant.

Before BAILEY and MANIAN, Examiners in Chief, and ANGEL, Acting Examiner in Chief.

MANIAN, Examiner in Chief.

This appeal is from the final rejection of claims 3 to 6, inclusive. The remaining claims in the case, namely claims 1, 2, and 7 to 11, inclusive, have been allowed.

No references have been relied on in the Answer.

Claims 3 to 6, inclusive, are finally rejected as "being nothing more than an obvious manner of producing applicant's article", reliance being made on the holdings in the cases of In re Larsen, 130 USPQ 209, Wirebounds Patents Co. et al. v. Gibbons Box Co., 25 F.2d 363, and Ex parte Trevette, 1901 C.D. 170. The examiner also refers to Section 706.03(q) of the Manual of Patent Examining Procedure in support of his position that method claims may be rejected on the ground relied on notwithstanding the allowance of claims to the article produced thereby.

[1] After a careful consideration of all of the arguments presented and authorities relied on by the appellant in his brief, reply brief and at the oral hearing and by the examiner in his Answer, we are of the opinion that the rejection of the claims is not tenable and is not, therefore, sustained. We find merit in appellant's contention that it is not apparent whether the invention lies in the article or in the method of producing the same, in which case these claims should be allowed along with the allowance of the claims to the article, consonant with the holding in the case of In re Conover, 49 CCPA 1205, 134 USPQ 238, which decision was called to our attention at the oral hearing. We also find merit in appellant's argument relative to the importance of the sequence of steps set forth in the claims at bar, namely the step of pressing the paperboard plate into the central pocket, etc., *after* the tubes have been formed and secured in upright position to the central portion to define said central pocket. This sequence of steps facilitates assembly and ensures a better reinforced article than a procedure wherein the plate is applied to the central portion of the blank prior to forming the tubes and pocket, for reasons given [2] on page 9 of the brief. The said sequence of steps must be shown to be old by the citation of art, and not by argument, to establish its obviousness and support the rejection.

In regard to appellant's reliance on the holding in the case of Ex parte Symons, 134 USPQ 74, attention is called to the later holding by a majority of the Board of Appeals in the case of Ex parte Packard, 140 USPQ 27.

The decision of the examiner is reversed.

Patent Office Trademark Trial and Appeal Board

WALTER KIDDE & COMPANY, INC. v. MONTGOMERY MEDICAL PRODUCTS, INCORPORATED

Decided July 27, 1965

TRADEMARKS

1. Acquisition of marks—Use by plurality of persons (§ 67.085)

Prior to junior party's use, senior party had enjoyed a public use of mark; such public use had come to junior's attention; by this use, senior acquired rights in mark sufficient to preclude registration by subsequent user.

Trademark interference No. 6,191 between Walter Kidde & Company, Inc., application, Serial No. 159,070, filed Dec. 13, 1962, and Montgomery Medical Products, Incorporated, application, Serial No. 153,190, filed Sept. 14, 1962. Montgomery Medical Products, Incorporated, held entitled to registration; registration to Walter Kidde & Company, Inc., refused.

ERNEST A. JOERREN, Belleville, N.J., for Walter Kidde & Company, Inc.

JOHN B. DICKMAN III and ROBERT J. PATCH, both of Washington, D.C., for Montgomery Medical Products, Incorporated.

Before LEACH, WALDSTREICHER, and LEFKOWITZ, Members.

WALDSTREICHER, Member.

An application was filed December 13, 1962 by Kidde Manufacturing Company, assignor to Walter Kidde & Company, Inc., to register "INFLATOMATIC" for "control heads for the valve of containers of gas under pressure, for inflating blood pressure cuffs." Use since on or about June 13, 1960 was asserted.

An application was filed on September 14, 1962 by Montgomery Medical Products, Incorporated to register "INFLATOMATIC" for a tourniquet cuff. Use since on or about December 16, 1960 was asserted.

An interference was instituted, in connection with which both parties filed testimony and exhibits.

According to the testimony in behalf of the junior party, the junior party, during the period June 1, 1960 to April 1, 1961, engaged in a development project concerning inflation gear for a blood pressure cuff. The device was intended to inflate, in conjunction with a source of compressed gas, a sphygmo-